



INERIS

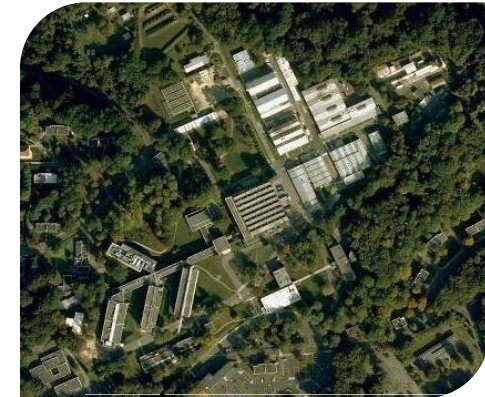
Assessing and reducing risks for a sustainable development

→ Turn standardization needs into ref. tools & methods, materials, work item and validated methods

INERIS:

Public Body having industrial activities, delivering an assessment based on the experimental approach, the modeling and the knowledge of the industry

- Long-time experience of the industrial world (> 60 years)
- under the trusteeship of the Ministry in charge of Ecology
- Multidisciplinary teams : chemistry, physics, life science, economy, sociology, medicine...
- An annual budget of 70 M€ :
- A staff of 600, including 350 engineers and researchers
- Full scale tests facilities (animal facilities, mesocosm, physics, chemistry and biology labs, pyrotechnic zone, hazard bench...
- Headquarters extend to 50 ha
- 25 000 m² of laboratories
- More than 1 000 French and international customers/ year
- 50 PhD students & 15 post-doctoral fellowships



A synergy between services for private customers, research activities and technical support for regulators

Expertise



Prevention of industrial and technological risks.



Prevention of risks associated with chemical substances.



Participation in the development, dissemination and sharing of best technologies and best practices.

INERIS Facilities and knowledge on NanoTech Risk Assessment

PROCESS SAFETY

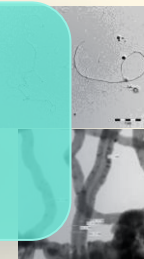
- Fire, explosion hazards
- Loss of containment
- Safety parameters
- Molecular modeling



Battery before and after fire test

METROLOGY

- On-line monitoring
- Sampling & characterization
- Instrumental calibration
- Nano generation tools



Online CNT detection unit

PRODUCTS CHARACTERIZATION NANOBENCH

- Physico-chemical properties
- Use and aging (mechanic stress...)
- End of life (recycling, burning)



Calorimeter Tewarson
ASTM E 2058 – NFPA 287

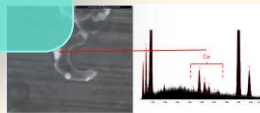
TOXICOLOGY

- Experimental (stress, inflam., genotox..)
- In vitro & In-silico (QSARs, TK, PBPK...)
- Inhalation exposure system (nanomaterials)

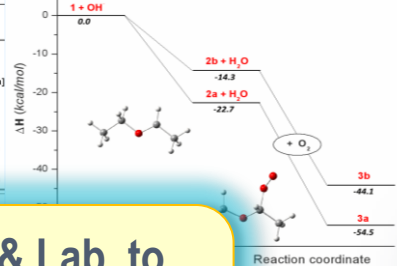
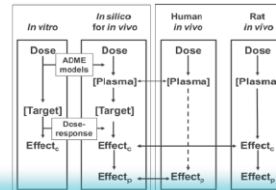


ECOTOXICOLOGY

- Experimental (Ageing, OECD)
- Large scale (mesocosm)



Nano-Safety Lab



MODELISATION

- nucleation, agglomeration
- Reactivity-Transport
- QSARS, QSPRs, Q. Meca.

Help Industries & Lab. to
develop safer nanotech.
Processes & products

RSIK ANALYSIS

- "Control banding" tools
- Semi-quantitative risk assessment
- Safety barriers management
- Intrinsic safety

EXPOSURE ASSESSMENT

- Occupational exposure
- Accidental exposure scenarios
- Environmental exposure

GLP facilities

STANDARDIZATION

- nanoREACH, ANSES
- ISO, CEN & AFNOR
- OECD – WPNM

SOCIO-ECONOMIC ANALYSIS

- Integration of LCA and LCC results
- Cost/benefit /efficiency (CBA, CEA)
 - Multi-criteria analysis (MCA)

TRAINING

- Workers, H&S dept.
- nanosafety /workplace
 - risk assessment

CERTIFICATION

- Workers, H&S, products
- NanoCert
 - ElliCert Batteries



French national platform dedicated to life science

→ Include an ENM inhalation system / In-vivo/ In-vitro

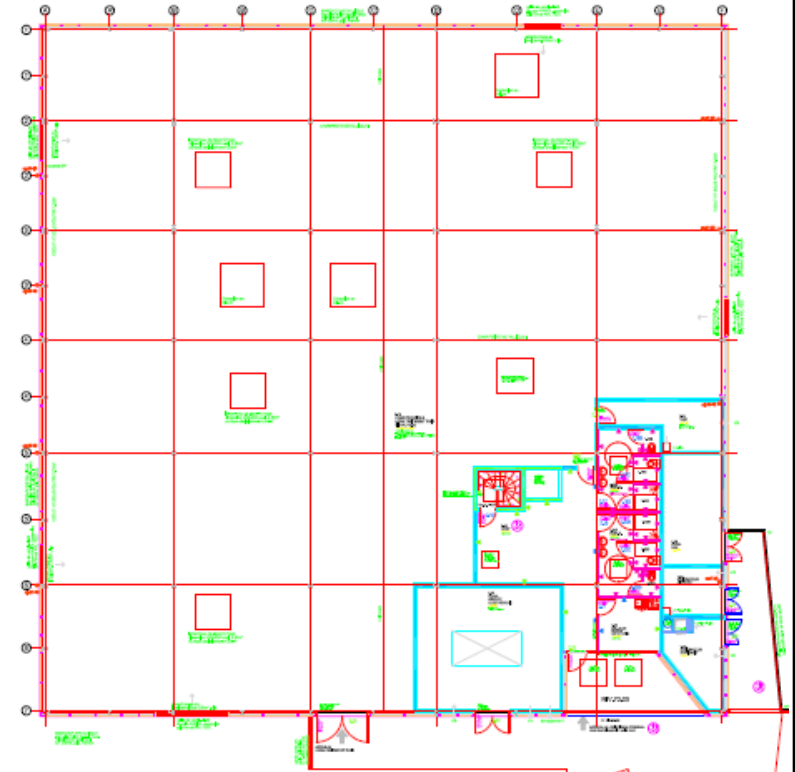
3R / The use of in vitro and in silico methods, validated by relevant in-vivo data, to predict toxicokinetics and toxicodynamics of ENM



→ Include a dedicated zone for Inhalation exposure studies on nanomaterials -> vitro & vivo

The complete system will meet EC Safety standards, follow REACH, FDA, EPA, GHS, KFDA and OECD (TG-403, TG-412, TG-413) Guidelines and moreover will fulfill GLP requirements. In addition, some nanoparticles generation and monitoring modules fulfill ISO 10801 and ISO 10808 standards

→ An oriented Good Lab Practice Laboratory
Above state of the art (atm. Generation, metrology...)



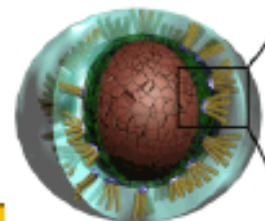
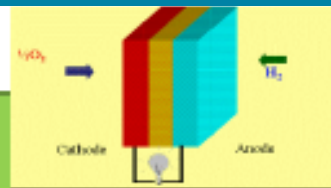
L'INERIS, French leadership and European partnerships

**INERIS:
Acteur
National et
Européen en
NanoSécurité**



MARINA (Managing Risks for Nano-Materials)
Risques accidentels, relargage massif

DEMCAMER
(Sécurité de nouveaux procédés réacteurs nano-membranaires)



NANOCARA
'Caracterisation de procédés de fabrication de nanoparticules



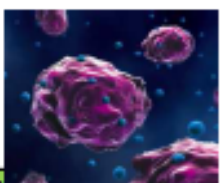
NANOTRANS:
Translocation des nanoparticules à travers les barrières biologiques : validation de modèles cellulaires au moyen de protocoles standardisés.



NANOSAFE
(Safe production and use of nanomaterials)



ImpecNano
Impact environnemental des nanomatériaux: exposition via leur cycle de vie et écotoxicité



SAPHIR
(Safe integrated and controlled production High tech Multifunctional NMP)



QNANO
(Quality in Nanomaterials Testing Standardisation des protocoles Tox et EcoTox)

NANODEVICE
(Device for airborne ENP at workplaces)

NANOFOL
(nanovectorisation des médicaments par folate based nanodevices-diagnosis, therapy)

Genesis: Production industrielle de CNTs

2008: 4 ETP
2009: 12 ETP
2010: 15 ETP- 2M€

Political perspective / Standardization needs

European standardization conference

"Innovation and market access through standards"
(Berlin, 27 March 2007)

Günter Verheugen, Vice-President of the EC



- "We must prepare Europe for the rapid political, economic and cultural challenges that affect and threaten us."
- "I can justifiably claim that, as far as European industry is concerned, European standardization is a trump card in global markets."



Political perspective / Standardization needs

- At the **World Economic Forum** in Davos 2007 the German Chancellor Angela Merkel emphasized the importance of technical standards
- Standardization has been recognized by the governments as a tool for promoting innovation
- Research and innovation are to be more closely interlinked with standardization

 **Goal:** Creating optimum conditions for future innovations and promoting their marketability.



Political perspective / Benefits of European Standards

- Standardization is an efficient tool for transposing the results of research to support the Single European Market and to strengthen European competitiveness in a global economy
- It fosters technical progress and innovation
- It helps to disseminate awareness and knowledge
- It helps to share good practices among all stakeholders, including:
 - industry at large & small and medium-size enterprises
 - public authorities and regulators as standards users
 - academia and the research community
 - consumers, etc
- It provides an opportunity for better regulation:
 - ‘Self regulation’ by the market and best practice benchmark
 - A co-regulation approach in Europe since 1985



Political perspective / Standardization needs for ENM

- Mandate M/461 identifies four areas for standards development:
 - Methodologies for nanomaterial characterization in the manufactured form and before toxicity and eco-toxicity testing;
 - Sampling and measurement of workplace, consumer and environment exposure
 - Methods to simulate exposures to nanomaterials
 - H, S & E (health, safety and the environment)
- The first three of which are covered in Annex I and the fourth in Annex II of the mandate M/461.



Standardization needs for ENM

- ***Annex II - Health, Safety, and Environment***

Elaboration of a series of guidances: (examples from the list)

- Guidance on safe handling of manufactured nanoparticles and other nanoscale entities;
- Guidance on a common data-format for an integrated analysis for risk assessment;
- Guidance on integrated testing strategies (ITS) and integrated risk assessment;
- Guidance on detection and identification of nanoparticles and other nanoscale entities;
- Protocols for the characterization of manufactured nanoparticles from aerosols and from environmental sources, including sampling, sample stabilization, agglomeration, aggregation, etc.
- Guidance on nano-material characterization prior to, or in association with toxicity testing;
- Guidance on sample preparation for toxicity testing, toxicokinetic and ecotoxicokinetic (air, water, soil) studies on nanoparticles and other nanoscale entities;
- Validated test methods for in vivo toxicology and toxicokinetics of nanoparticles and other nanoscale entities;
- Protocols for in vitro toxicology evaluation of nanoparticles and other nanoscale entities;
- Protocols for evaluating the effects of short and long term dermal, nasal, oral and pulmonary exposure to, elimination of, and fate determination for nanoparticles and other nanoscale entities;
- Fast track protocols for predicting the toxicity and ecotoxicity for classification of nanoparticles and other nanoscale entities, particularly for identifying and tracking the most dangerous ones in the framework of the REACH directive;
- Protocols for determining the explosivity and flammability of nano-powders (for transport, handling and storage);
- Protocols for risk assessment of potentially hazardous nanoparticles and other nanoscale entities;
- Protocols for risk management that specifically refers to potential nanotechnology hazards;
- Protocols for whole life cycle assessment of nanoscale materials, devices and products.



List of TC concerned by the mandate M/461

CEN/TC 137	Assessment of workplace exposure to chem & biolo agents
CEN/TC 138	Non-destructive testing
CEN/TC 162	Protective clothing including hand, arm protection and lifejackets
CEN/TC 195	Air filters for general air cleaning
CEN/TC 230	Water analysis
<u>CEN/TC 352</u>	<u>Nanotechnologies</u>

ISO/TC 24/SC4	Particle characterization
ISO/TC 142	Cleaning equipment for air and other gases
ISO/TC 194	Biological evaluation of medical devices
ISO/TC 201	Surface chemical analysis
ISO/TC 202	Microbeam analysis
<u>ISO/TC 229</u>	<u>Nanotechnologies</u>

IEC/TC113	Nanotechnology standardisation for electrical and electronic products and systems
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nanoSTAIR overview

EU-VRI

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→ <http://www.nanostair.eu-vri.eu>

Title: ***Establishing a process and a platform to support standardization for nanotechnologies implementing the STAIR approach***

From Sept. 2012 to March 2014

...to build a sustainable process and platform in the field of nanotechnologies to support the transfer of knowledge gained through research to documentary standards in the context of the STAIR approach



EUROPEAN COMMITTEE
FOR STANDARDIZATION



Finnish Institute of
Occupational Health



STAIR: a step by step process

Think about the
'standardization
potential'
at every step of
the proposal
development





STAIR process → context

- Still necessary to promote standardization activities in the research community
- Provide support to researchers to orient themselves in the standardization activities
- “Close the gulf” between research and standardization by providing more opportunities for linkage
- **In concrete:**
 - Implement / Use the STAIR approach
 - Develop a platform to inform, connect and start standardization activities based on research results

nanoSTAIR overview

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...to build a sustainable process and platform in the field of nanotechnologies to support the transfer of knowledge gained through research to documentary standards in the context of the STAIR approach



nanoSTAIR turbine

TILL HERE:
"Partnership to accelerate the emergence of work items"

FROM HERE:
"Normal standardisation process" but all on track and well prepared (support from nanoSTAIR to have a good start)

TOPICS FOR STANDARD COMING FROM R&D PROJECTS

Pooling resources to launch standardization work items (WP2)

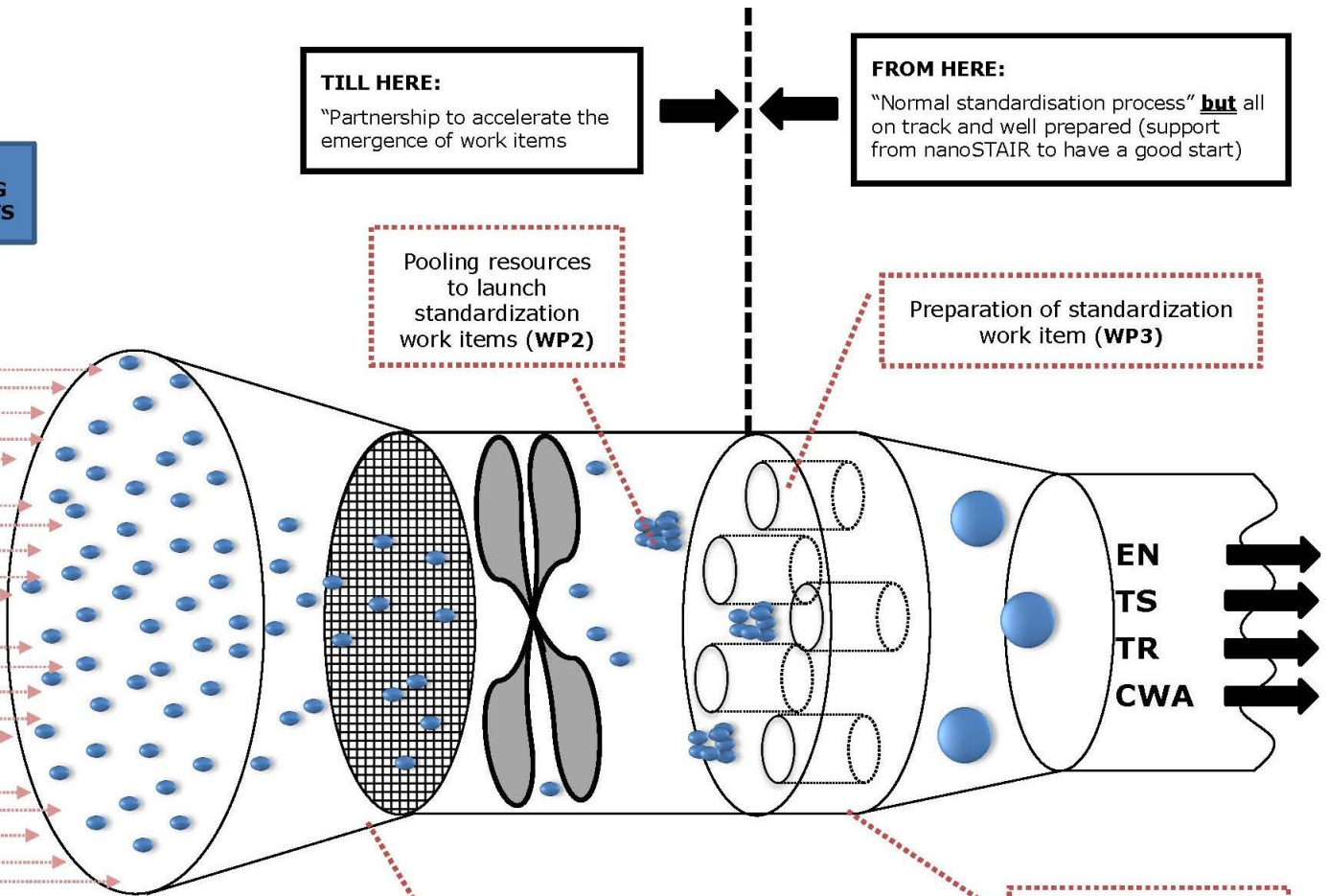
Preparation of standardization work item (WP3)

Screening and identification of standardization opportunities (WP1)

Tool box & dissemination (WP4)

- International initiatives
- National Programmes
- Industry
- EU FP7 EUREKA ...

Support from NanoSafety Cluster NanoFutures





WP1 Screening & identification of std opportunities

Criteria to identify & select the candidates for new work item/

Process for auto pooling

→ matrix of criteria, bottom up candidates

→ auto top down screening of candidate

WP2 Pooling resources to launch std work items

- Identification of the needs from various stakeholders (gov, eu, ngos, ...)
- Identification of both experts & projects
 - matrix of needs, long term stable linkage

Eg. Going up to expert/ project/ item mining ?

WP3 Verification of the approach : preparation of standardization work item

Inflate WI in existing TC, initiate NWIP, initiate action for WI not in TC → CEN WA

→ initiate NWIP for a WI inflated in a TC

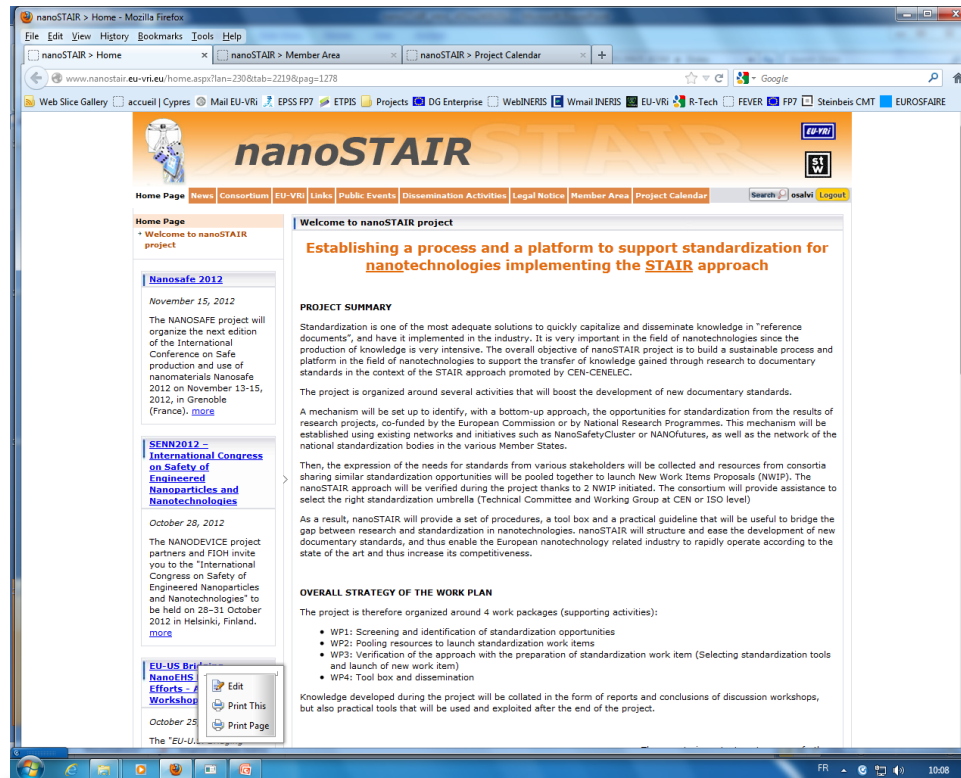
→ or a CEN Workshop Agreement if relevant

WP4 Tool box and dissemination

- nanoSTAIR practical guideline to bridge the gap between research and standardization
- a website for information exchange among partners and other stakeholders
- brochures and leaflets

Further information

<http://www.nanostair.eu-vri.eu/>



nanostair@eu-vri.eu

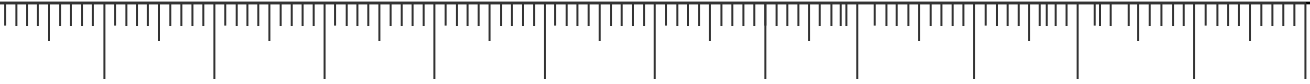


A common European approach to the regulatory testing of nanomaterials

NANoREG

Status : negotiating .../2012–2015

→ 60 partners, 13 European memb states, 42 M€



The process from hazard identification to risk assessment, followed by risk management, mitigation, and avoidance, forms the only acceptable route for evaluating MNMs. The approach to achieve this process will be:

1. collect and evaluate all existing data, from ongoing and completed national, EU and international sources. Where do we stand at present.
2. define the boundaries, i.e. which fields will be excluded.
3. make a gap analysis to identify those nanomaterials where regulatory and testing input is needed either just to give additional guidance, or to make modifications to existing testing schemes, or for where new methodologies are needed.
4. Agree on test methods based on relevant data.
5. Establishing a forum to decide how to implement changes to the guidance and guidelines, a core task in the project.
6. Agree the data storage and management from the project.
7. Ensure open and transparent dissemination.



The wider scientific and technical objectives of this project are:

- provide legislators with a set of tools for risk assessment
- develop for the long term, new testing strategies adapted to a high number of nanomaterials where many factors can affect their environmental and health impact.
- establish a close collaboration among authorities and industry with regard to the knowledge required for appropriate risk management
- create the basis for common approaches, mutually acceptable datasets and risk management practices.



NANO PREMISS

Develop a global risk management framework for production and disposal/recycling processes.

Focus : on potential impacts outside the plant (environment or populations) /from accidental or chronic releases of ENM

→ Clustering validated methods → Industrial safety Tool Box

NMP 2013.1.3-1 Safety in nanoscale production and products

Some ENERO lab are partners of the project
Leader : INERIS (Bruno.debray@ineris.fr)

INERIS

maîtriser le risque |
pour un développement durable |



Thank You For your attention

Further information :

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